

Notice of Allowability

Application No.

10/589,902

Examiner

Zachariah Lucas

Applicant(s)

WAKITA ET AL.

Art Unit

1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to the amendment of July 22, 2009, and the interview of August 19, 2009.
2. ☒ The allowed claim(s) is/are 1,2,5-21 and 24.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some* c) ☐ None of the:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).
- * Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
- (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|--|---|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892) | 5. <input type="checkbox"/> Notice of Informal Patent Application |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 6. <input checked="" type="checkbox"/> Interview Summary (PTO-413),
Paper No./Mail Date <u>8/19/09</u> . |
| 3. <input type="checkbox"/> Information Disclosure Statements (PTO/SB/08),
Paper No./Mail Date _____ | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit
of Biological Material | 8. <input type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| | 9. <input type="checkbox"/> Other _____. |

/Zachariah Lucas/
Primary Examiner, Art Unit 1648

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DETAILED ACTION

1. Claims 1, 2, 5-21, and 24 are pending in the application.
2. In the prior action, the Final action mailed on April 1, 2009, claims 1, 2, 5-27 were pending, with claims 1, 2, 5-11, 22, and 27 under consideration and rejected; and claims 12-21 and 23-26 withdrawn from consideration.
3. In the After-Final responses of July 1 and 22, 2009, and pursuant to the interview of July 27, 2009, the Applicant amended claims 13 and 15-21; and cancelled claims 22, 23, and 25-27.

EXAMINER'S AMENDMENT

4. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Susan W. Gorman on August 19, 2009.

The application has been amended as follows:

Claim 11 has been amended by deletion of the phrase "A cell" in line 1 of the claim, and insertion of the phrase "An isolated cell" in its place.

Claim 18 has been amended to read as follows: - - A method for producing a hepatitis C immunogenic composition, comprising mixing the particles according to claim 13 with a pharmaceutically acceptable excipient. - -

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The amendment to claim 11 avoids potential issues under 35 USC 101, and the amendment to claim 18 clarifies the claim scope.

Claim Rejections - 35 USC § 112

5. **(Prior Rejection- Withdrawn)** Claim 27 was rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In view of the cancellation of the claim, the rejection is withdrawn.

6. **(Prior Rejection- Withdrawn)** Claims 5 and 27 were rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. In view of the cancellation of claim 27, and the limitation of claim 5 to a replicon comprising SEQ ID NO: 13, the rejection is withdrawn.

Claim Rejections - 35 USC § 103

7. **(Prior Rejection- Withdrawn)** Claims 1, 2, 5-11, 22, and new claim 27 were rejected under 35 U.S.C. 103(a) as being unpatentable over Kato et al. (Gastroenterol 128:1808-17-*supra*) in view of Ikeda et al. (J Virol 76:2997-3006) and of EMBL AB047639. In view of the arguments of July 1, 2009, the rejection is withdrawn.

Double Patenting

8. **(Prior Rejection- Withdrawn)** Claims 1-5 and 22 were provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-

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13 and 21 of copending Application No. 10/558155 in view of Ikeda et al. (supra). In view of the arguments of July 1, 2009, the rejection is withdrawn.

Conclusion

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachariah Lucas whose telephone number is (571)272-0905. The examiner can normally be reached on Monday-Friday, 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary B. Nickol can be reached on 571-272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Zachariah Lucas/
Primary Examiner, Art Unit 1648